

Application No. 10/578,171
Amendment Dated: May 19, 2009
Reply to Office Action of: February 19, 2009

Remarks/Arguments

Reconsideration and allowance of the above-referenced application are respectfully requested.

The applicant acknowledges with appreciation the courtesy of the Examiner in holding a telephone interview with the applicant and applicant's counsel on May 15, 2009. During the interview, the applicant provided commentary on the Sayler reference and indicated that the independent claims were going to be amended to include the language --an outer surface of-- and the term --biocompatibility—in order to even further distinguish them from the Sayler and Soykan references. (The actual amendment of claim 37 filed herewith uses the phrase “increasing the lifespan of” rather than referring to biocompatibility). The applicant also indicated that claims 9, 66 and 75 were going to be amended to overcome the 35 U.S.C. Sec. 112 rejections, and that the original IDS correctly lists the patent number of the Moussy reference.

Objections of the Specification

The objections to the specification are believed to be overcome by the submission of a CD containing the sequence listing of Fig. 22 and by amending the Brief Description of the Drawings on page 8 of the specification.

Status of the Claims

Claims 1, 2, 4, 9, 14-16, 19, 25, 27, 28, 37-39, 51, 52, 54, 59, 66 and 68-78 are pending. Claims 1, 9, 16, 27, 28, 37, 38, 51, 52, 54, 59, 66, 69, 74 and 75 are amended, claims 76-78 have been added, and claims 3, 20 and 67 are canceled without prejudice. Basis for the amendments to claims 1 and 28 can be found in various parts of the specification and drawings, including at page 4, lines 6-8 and page 10, line 25 to page 11, line 19, and in canceled claim 3. Basis for the amendments to claim 37 can be found in those same parts of the application and also on page 4, lines 8-10 of the specification. Basis for the amendments to claims 51, 52, 54 and 69 can be found at page 10, lines 25-30 and in the examples. Basis for the amendment to claim 66 can be found in original claim

Application No. 10/578,171
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36. Claim 76 has basis in the former version of claim 75. Claim 77 has basis in a specification at page 11, lines 1-5. Claim 78 has basis in Fig. 38 and the corresponding description in the specification.

Rejections Under 35 U.S.C. Sec. 112

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. This claim has been amended in order to overcome this rejection. The language of amended claim 66 now more closely parallels the language of original claim 36. Reconsideration is requested.

Claims 9 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Claim 9 has been amended to change "comprising" to --is--. Claim 75 has been amended to depend from claim 54. Reconsideration is requested.

Rejection Under 35 U.S.C. Sec. 102

Claims 1-4, 9, 14-16, 19, 20, 25, 27, 28, 37, 39, 51, 52, 54, 67, 68, 69, 70, 72 and 73 are rejected under 35 U.S.C. 102(e) as being anticipated by Sayler et al. (U.S. Patent No. 6,673,596; filed December 2, 1999). Reconsideration is requested.

The present application is directed to a system for enhancing the useful life and/or function of an implant by surrounding the implant with an artificial tissue system that enhances biocompatibility of the implant and a biological system. In contrast, Sayler is directed to the construction of sensors. More particularly, Sayler discloses integrated circuit devices that detect selected analytes in fluids when implanted in the body of an animal. The sensors can consist of bioengineered cells entrapped in suspension, or cells encapsulated in a polymeric matrix (col 23, lines 33-56). Thus, In Sayler the matrix is within the sensor and is part of the sensor, while in the claims of the present application the matrix is in contact with the outer surface of the implantable device, as is recited in independent claims 1, 18 and 37. Furthermore, the sensor of Sayler does not

Application No. 10/578,171
Amendment Dated: May 19, 2009
Reply to Office Action of: February 19, 2009

promote biocompatibility of an implantable device with a biological system as is recited in independent claims 1, 28, and does not increase the lifespan of the implant device, as is recited in claim 37, but instead detects contents of a biological system.

Dependent claims 2, 4, 9, 14-16, 19, 25, 27, 51, 66, and 70-74 depend directly or indirectly upon claim 1 and are believed to be patentable for the same reasons as claim 1. Dependent claims 52, 68 and 69 depend directly or indirectly from claim 28 and are believed to be patentable for the same reasons as claim 28. Dependent claims 39, 54, 59, 74, 75 and 76 depend directly or indirectly upon claims 37 and are believed to be patentable for the same reasons as claim 37. Thus, Sayler does not anticipate claims 1, 2, 4, 9, 14-16, 19, 25, 27, 28, 37, 39, 51, 52, 54, 68, 69, 70, 72 and 73 of the present application. Reconsideration is requested.

Rejection Under 35 U.S.C. Sec. 103

Claims 28, 37, 38, 59, 66, 70, 71 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sayler et al. (U.S. Patent No. 6,673,596; filed December 2, 1999), in view of Soykan et al. (U.S. Patent Application Publication No. 2001/0000802; effective filing date: December 20, 2000). Reconsideration is requested.

The deficiencies of Sayler in connection with independent claims 28 and 37 are explained above in the discussion of the 102 rejection. Soykan is directed to an implantable drug delivery system containing cells that are capable of producing and releasing a therapeutic agent for treatment of a disease, such as coronary artery disease, upon application of a stimulus, such as an electrical stimulus. The system can include a sensor which is separate from the implant and typically is located in component 22 of Fig. 2 of Soykan (see col. 7, lines 4-5) spaced apart from the implant. As mentioned above, independent claim 28 of the present application has been amended to provide that the biological matrix is in contact with an outer surface of the implantable device, and to provide that the

Application No. 10/578,171
Amendment Dated: May 19, 2009
Reply to Office Action of: February 19, 2009

cells in the matrix promote biocompatibility between the implantable device and a biological system. There is no disclosure or suggestion in Soykan of the promotion of biocompatibility between an implant and a biological system. Thus, Soykan does not make up for this deficiency of Sayler and the combination of references does not render obvious independent claim 28 of the present application.

Independent claim 37 has been amended to provide that the biological matrix is in contact with an outer surface of the implantable device, and to provide that the cells and/or the matrix promote biocompatibility between the implantable device and a biological system. There is no disclosure or suggestion in Soykan of the promotion of biocompatibility between an implant and a biological system. Thus, Soykan does not make up for this deficiency of Sayler and thus the combination of references does not render obvious independent claim 37 of the present application.

Dependent claims 38, 59 and 74 depend directly or indirectly upon claim 37 and are believed to be patentable for the same reasons as claim 37. Claims 66, 70 and 71 depend directly or indirectly upon claim 1 and are believed to be patentable for the same reasons as claim 1.

New claim 78 is similar to claim 54 except that it does not require the presence of cells. Instead, the basement membrane itself promotes biocompatibility between the implantable device and the biological system.

Information Disclosure Statement

The attached IDS cites a CIP of the Moussy reference cited that is listed in the original IDS. It is noted that the original IDS correctly lists the patent number for Moussy as US Patent No. 6,497,729. Consideration of both Moussy references is requested.

Application No. 10/578,171
Amendment Dated: May 19, 2009
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In view of the above, it is believed that this application is in condition for allowance, and such a Notice is respectfully solicited.

Respectfully submitted,

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